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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/531,877 | 08/01/2005 | Jindrich Richter | 270131US0PCT | 4537 |
| 22850 | 7590 | 09/13/2006 | EXAMINER | |
| C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | AULAKH, CHARANJIT | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/531,877 | Applicant(s) RICHTER ET AL. | |
| | Examiner Charanjit S. Aulakh | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/1/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. According to a preliminary amendment, the applicants have amended claims 3-16 and added new claim 17.
2. Claims 1-17 are pending in the application.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 16 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cazer (WO 01/56983, cited on applicant's form 1449).

Cazer discloses monohydrate and hemipentahydrate forms of sodium salt of risedronic acid. The pharmaceutical composition comprising monohydrate and hemipentahydrate forms of sodium salt of risedronic acid (see claims 9 and 10) disclosed by Cazer clearly anticipate the instant claim. It is of note that the compound will not maintain its hydrate form in pharmaceutical composition and the pharmaceutical utility is due to compound itself.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cazer (WO 01/56983, cited on applicant's form 1449).

Cazer discloses monohydrate and hemipentahydrate forms of sodium salt of risedronic acid. In table 1 (see page 5), Cazer discloses preparation of hydrate forms of sodium salt of risedronic acid with water content in the range of 5.7% to 13.1%. Cazer differs from the instant claims that it does not mention actual % of sodium content in the hydrate form of risedronic acid. However, Cazer also prepares hydrates of sodium salt of risedronic acid and therefore, it would be obvious to one skilled in the art to prepare hydrate forms of risedronic acid with different %age of sodium content unless applicants provide evidence of unexpected results of superior stability, activity etc. of their hydrates as compared to hydrates of Cazer.

7. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aronhime (WO 03/086355, cited on applicant's form 1449).

Aronhime discloses polymorphs and pseudopolymorphs of risedronate sodium and pharmaceutical compositions containing these polymorphs or hydrates (see claims 1-137). On page 20, Aronhime discloses preparing different polymorphs (hydrates) with

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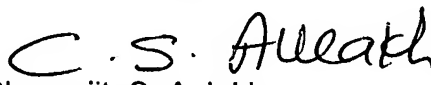
varying amounts (0% to 100%) of water content using 1 to 2 equivalents of sodium hydroxide. Aronhime differs from the instant claims that it does not mention actual % of sodium content in the polymorph or hydrate form of risedronate sodium. However, Aronhime also prepares hydrates of sodium salt of risedronic acid and therefore, it would be obvious to one skilled in the art to prepare hydrate forms of risedronic acid with different %age of sodium content unless applicants provide evidence of unexpected results of superior stability, activity etc. of their hydrates as compared to hydrates of Aronhime.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Charanjit S. Aulakh
Primary Examiner
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